

## **Title**

**Rationale, design and baseline data from the PREPARE  
(Pre-diabetes Risk Education and Physical Activity  
Recommendation and Encouragement) programme study: a  
randomized controlled trial**

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## Abstract:

*Objective:* The PREPARE programme study is a randomized controlled trial which aims to determine whether structured education can be used to increase physical activity and improve glucose tolerance in individuals with impaired glucose tolerance (IGT). This paper outlines the rationale, design and baseline data from the PREPARE programme study.

*Methods:* Individuals with IGT were recruited from ongoing diabetes screening programmes. Outcomes included an oral glucose tolerance test, physical activity (piezoelectric pedometer) and psychological determinants.

*Results:* 103 individuals (male n=65; female n=38) were recruited, 28% of whom were from a South Asian ethnic background. At baseline the participants mean age and BMI were  $64 \pm 9$  years and  $29.4 \pm 4.5 \text{ kg/m}^2$  respectively. Steps per day were associated with 2-h glucose ( $\rho = -0.22$ ,  $p = 0.03$ ), fasting glucose ( $\rho = -0.22$ ,  $p = 0.04$ ), HDL-cholesterol ( $\rho = 0.23$ ,  $p = 0.02$ ), triglycerides ( $\rho = -0.22$ ,  $p = 0.03$ ) and body fat percentage ( $\rho = -0.26$ ,  $p = 0.01$ ). Mean self-efficacy scores were significantly ( $p < 0.01$ ) higher for walking than for any other form of exercise. Participants reported high levels of concern about their IGT status but were confident that exercise would help treat/control IGT.

*Conclusion:* This study demonstrates the importance of developing effective physical activity and self-management programmes for individuals with IGT.

*Practical implications:* This study provides a detailed framework for the promotion of physical activity in a population identified with an increased risk of developing type 2 diabetes which, if successful, could feasibly be implemented in a primarily health care or community setting.

Key words: illness perceptions, impaired glucose tolerance, physical activity, structured education, walking

# 1. Introduction

## 1.1 Background

The prevalence of type 2 diabetes is reaching epidemic proportions and the costs associated with its treatment are set to represent a serious clinical and financial challenge to national health systems [1]. It is therefore of primary importance to develop diabetes prevention strategies in high risk populations to counter this worrying trend. Individuals with impaired glucose tolerance (IGT) have an increased risk of developing type 2 diabetes and cardiovascular disease compared to those with normal glucose tolerance [2] and are therefore a suitable population for diabetes prevention initiatives.

Although physical activity has consistently been associated with a reduced risk of developing diabetes [3], there is no evidence that traditional multi-factor diabetes prevention programmes have been successful at initiating clinically significant increases in physical activity [4]. More broadly, it has also been reported that interventions aimed at promoting physical activity make use of methods that would be difficult to deliver in usual health care practice [5], and that there is a gap between physical activity intervention research and the delivery of evidence-based practice [6]. Furthermore, physical activity interventions that have been delivered in primary care have met with limited success, particularly over the longer term [7,8]. Therefore there is a need to develop successful physical activity interventions that are appropriate for a primary health care or community setting. This conclusion is also true of diabetes

prevention programmes in general where it has pointed out that such initiatives will have limited feasibility and success unless they are tailored to the specific requirements of national health care services [9,10]. Whilst traditional diabetes prevention programmes are based on multi-factor lifestyle interventions [11,12], it has been shown that single-factor physical activity interventions are more effective at initiating physical activity behaviour change in a health care setting [13] and improving glycaemic control in individuals with type 2 diabetes [14]. Therefore, given the limited success of diabetes prevention programmes at promoting physical activity [4], robustly tested single-factor physical activity interventions are needed [15].

The Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE) programme study is a randomized controlled trial designed to test the efficacy of structured education at promoting physical activity and improving glucose tolerance in individuals identified with IGT. The aim of this paper is to describe the rationale, design and baseline data from the PREPARE programme study and to describe the relationships between measured psychological, behavioural and clinical variables. This detailed examination of the study's theoretical underpinning, recruited participants and correlations between measured variables will help contextualize future outcomes.

## ***1.2 Rationale for the PREPARE programme***

Patient education has been advocated as a fundamental part of patient care for individuals diagnosed with diabetes in the UK [16]. Whilst established structured

educational programmes for individuals with diabetes, such as the DESMOND programme [17], have been successful at initiating behaviour change in individuals with diabetes [18,19], structured education has not been tested as a method of promoting health behaviour and self-management in individuals identified with an increased risk of developing diabetes. As structured education is compatible with the infrastructure of many national health services, it is important to test whether this approach to patient care can be utilized to promote physical activity and improve health outcomes in at-risk populations.

In order to be effective it is important that interventions aimed at promoting physical activity and self-management are based on known learning techniques and health behaviour theory [16,20]. However, considering that there are more than 20 health behaviour theories and that many of these theories lack empirical evidence, choosing an appropriate theory on which to ground an intervention is problematic [21].

However, successful physical activity and multi-factor intervention programmes in individuals with IGT and diabetes, regardless of their theoretical underpinning, have consistently utilized methods that are central to Bandura's social cognitive theory [22], such as targeting barriers, self-efficacy and self-regulatory skills [11,23-26]. In particular it is increasingly recognized by Bandura and others that self-regulation is likely to be fundamental to the success of any health promotion intervention [20,27,28]. Self-regulatory models, such as Gollwitzer's implementation intentions [29], have been shown to be successful at initiating and predicting physical activity behaviour change [30-32]. Therefore in order to maximize physical activity behaviour change it is important that physical activity interventions are successful at promoting

self-regulatory and volitional skills as well as traditional motivational components, such as self-efficacy.

Along with traditional social cognitive constructs, perceptions and beliefs about identified illnesses/health conditions may also be important in interventions promoting health behaviours. Leventhal's common sense model postulates that individuals conceptualize any identified health threat in terms of the cause, consequences, identity, control/treatment and timeline associated with the threat and that these domains will influence subsequent coping behaviour [33]. Although illness perceptions have typically been overlooked in physical activity research, Leventhal's common sense model has been demonstrated across a wide range of patient groups [34] and recent findings have shown that illness perceptions and beliefs are closely linked to health behaviour change, including physical activity, in individuals with type 2 diabetes [19]. Although IGT differs from diabetes and other chronic diseases, in that it is not a recognized disease, individuals identified with IGT are nevertheless likely to form a set of perceptions and beliefs about IGT that may influence how they cope with the condition in the future. Therefore, any intervention aimed at increasing physical activity in individuals with IGT should target perceptions and beliefs around IGT.

### **1.3 Walking and the pedometer**

Physical activity interventions need to promote forms of physical activity that are appropriate and acceptable to their target populations. Walking has consistently been shown to be the preferred choice of physical activity in a wide range of populations and patient groups [23,35-37], including those with IGT [38]. Walking is also associated with fewer barriers than other forms of physical activity in black and minority ethnic populations [39]. It is therefore important that walking activity is promoted in interventions aimed at increasing physical activity in individuals with IGT.

The pedometer is widely recognized as a inexpensive tool which can aid the promotion of walking activity through its use as an objective self-monitoring tool. Pedometer intervention studies have consistently been shown to be successful at initiating physical activity behaviour change [40]. However, despite these promising findings the National Institute of Health and Clinical Excellence (NICE) has concluded that, whilst pedometers may be a useful tool in the promotion of physical activity, the success of pedometer intervention studies remains equivocal in a health-care setting [41].

## 2. Methods

### 2.1 Research design

The PREPARE programme study is a three-armed randomized controlled trial. The primary purpose of the study is to test the hypothesis that structured education can be effectively utilized to promote physical activity and improve glycaemic control in individuals identified with IGT. A secondary aim of the study is to test the hypothesis that providing participants with a pedometer and step per day goals will increase the effectiveness of structured education at promoting physical activity. We will measure the effectiveness of the pedometer version of the PREPARE programme against control conditions to test our primary hypothesis. The study was powered to detect a 1 mmol/l difference in post-challenge 2-hour blood glucose (2-h glucose) levels between the primary intervention and control group. Using a power of 80%, a significance level of 0.05, a standardized difference of 1 and allowing for a 50% drop-out rate, two groups of 34 individuals were required to test our primary hypothesis [42]. After including a third group of the same size to test our secondary hypothesis, a total of 102 participants was required. Given the relatively small sample size, participants were randomized using a block design and stratified by age and sex in order to increase the likelihood of randomization producing equivalent groups. Randomization was conducted using opaque envelopes and a randomly generated number sequence (SPSS, Chicago, USA) by a member of our research team with no prior knowledge of recruited individuals, other than their age and sex.



Participants will be followed-up at three months, six months and 12 months.

## **2.2 Treatment regimens**

Participants were randomized to receive either usual care, the PREPARE with pedometer use or the PREPARE programme without pedometer use.

The PREPARE programme is a single session group educational programme designed to promote increased physical activity, primarily walking activity, by targeting perceptions and knowledge of impaired glucose tolerance, physical activity self-efficacy, barriers, and self-regulatory skills. The programme is group-based and delivered to between 5 to 10 participants, is three hours long and uses a person-centred approach to patient education, based on Chaiken's dual process theory [43]. The PREPARE programme is divided into four modules. Table 1 gives a broad overview of the theoretical underpinning and weighting of each module. A brief dietary session was included as pilot work had revealed that diet is strongly linked to illness perceptions surrounding IGT. However, participants were not encouraged to set dietary goals or action plans.

The two versions of the PREPARE programme are identical, except that in the pedometer version participants are given, and shown how to use, a pedometer (SW-200, Yamax Corporation, Tokyo, Japan) and encouraged to set personalized steps per day goals based on their baseline ambulatory activity levels and step per day categories proposed by Tudor-Locke [44]; whereas in the alternative version

participants are encouraged to set physical activity goals based on generic exercise recommendations, such as 30 minutes of moderate intensity exercise on most days of the week [45]. Participants in both groups are provided with physical activity diaries. A comprehensive written curriculum was developed for each version of the PREPARE programme. Each PREPARE programme session was delivered by two educators. Educators held an undergraduate degree in a relevant discipline (dietician, sports scientist) and were trained to deliver the DESMOND curriculum [17], which is an established structured educational programme with a similar philosophy and theoretical underpinning to the PREPARE programme. In addition, all educators completed at least two pilot sessions of the PREPARE programme and received instructive feedback from an experienced and accredited DESMOND educator before delivering the PREPARE programme in the randomized controlled trial.

Individuals randomized to the two intervention groups also receive brief (10 minute) one-to-one follow-up counselling with a trained educator at their 3-month and 6-month clinical measurement session. There is no additional contact with the research team.

Participants randomized to the control group were sent a brief information sheet detailing the likely causes, consequences, symptoms and timeline associated with IGT, along with information about how physical activity can be used to treat/control the condition. No additional advice or encouragement is given to the control group.

### **2.3 Recruitment**

Participants were recruited from ongoing population-based diabetes screening programmes between September 2006 and March 2007. Individuals were invited to take part in the study if, at initial screening, they had IGT (2-h glucose of  $\geq 7.8$  mmol/l and  $< 11.1$  mmol/l and fasting glucose  $< 7.0$  mmol/l) [46] and had a body mass index (BMI) of  $25 \text{ Kg/m}^2$  or greater ( $23 \text{ Kg/m}^2$  or greater for those from a South Asian ethnic background) [47]. Individuals who reported taking steroids or who were unable to take part in moderate physical activity were excluded.

## **2.4 Measures**

The PREPARE study will be evaluated using biochemical variables, anthropometric and demographic variables, physical activity measures, as well as psychological variables.

### **2.4.1 Biochemical**

Participants arrived at their appointment for an oral glucose tolerance test after a 12-hour fast and 24 hours of avoiding vigorous-intensity exercise. Those who had a fasting or 2-h glucose level in the diabetes range [46] were called back for a second oral glucose tolerance test; if the participant had a fasting or 2-h glucose level in the diabetes range at the second test, a diagnosis of diabetes was confirmed and participants were referred to a specialist clinician for treatment.

Plasma glucose was measured using a glucose oxidase method on the Beckman Auto Analyzer (Beckman, High Wycombe, UK). Serum cholesterol was analysed using the cholesterol enzymatic assay (Abbott Clinical Chemistry, IL, USA). High density lipoprotein (HDL) cholesterol was analysed using the ultra HDL assay (Abbott Clinical Chemistry, IL, USA). Low density lipoprotein (LDL) was calculated using the Friedewald formula [48]. Serum triglyceride was analysed using the triglyceride glycerol phosphate oxidase assay (Abbott Clinical Chemistry, IL, USA).

#### **2.4.2 Anthropometric and demographic**

Arterial blood pressure is measured in the sitting position (Omron, Healthcare, Henfield, UK); three measurements were obtained and the average of the last two measurements was used. Body weight and body fat percentage (Tanita TBE 611, Tanita, West Drayton, UK), waist circumference (midpoint between the lower costal margin and iliac crest) and height are also measured. Information about current medication and smoking status along with ethnicity are also measured by questionnaire.

#### **2.4.3 Physical activity**

Physical activity was measured objectively using a pedometer and subjectively with a questionnaire. Sealed piezoelectric pedometers with a seven day memory (NL-800, New-lifestyles, USA ) were used for this study. These pedometers have been shown

to be one of the most accurate and reliable instruments on the market and are more sensitive than traditional spring-levered pedometers for use on overweight and obese individuals [49]. At baseline, all participants were fitted with a pedometer and instructed to wear it for seven consecutive days during waking hours and to keep a daily log of the time the instrument was worn. At the end of the seven day period participants returned the pedometers by post to the research centre where the data was extracted from the instrument and matched to the time the pedometer was worn. For the purposes of this study at least three valid days of data were required; a valid day constituted at least 12 hours of collected data. It has been shown that the average steps per day of any weekly three day combination is highly correlated with the average steps per day taken over the full seven day period; consequently, three or more days of data provides an acceptable measure of walking activity levels over seven consecutive days [50]. For the purposes of this study, individuals were classified as sedentary (<5000 steps per day) or active ( $\geq 5000$  steps per day) based on preliminary pedometer indices proposed by Tudor-Locke and Bassett [44].

The long last-seven-days self-administered format of the International Physical Activity Questionnaire (IPAQ) was also used to measure physical activity [51]. This questionnaire provides a comprehensive measure of walking and other moderate-to-vigorous activities carried out at work, in the home, as transport and during leisure time. The IPAQ questionnaire has been shown to correlate adequately ( $\rho = 0.4$ ) with accelerometer data in the United Kingdom [52]. Participants were classified as sedentary or active based on IPAQ guidelines [51]; these categories correspond to distinguishing between those who achieve the current exercise recommendations [45] and those who do not.

## **2.4.4 Psychological determinants**

### **Health-related quality of life**

Health-related quality of life was measured using the EQ-5D [53], which is a standardized questionnaire that was developed for use as a measure of health outcomes and defines health in terms of five dimensions: mobility; self-care; usual activities; pain or discomfort; and anxiety or depression. Data from the EQ-5D can be represented either as a health profile (EQ-5D<sub>profile</sub>) or a health index (EQ-5D<sub>utility</sub>) based on time trade-off data from England, UK, which was used to elicit utility weights for the EQ-5D.

### **Perceptions and perceived knowledge of IGT**

Perceptions and perceived knowledge of IGT were measured with the validated brief illness perceptions questionnaire [54]. This instrument uses a 10 point likert scale to measure five cognitive illness representations (consequences, timeline, personal control, treatment control, and identity), two emotional representations (concern and emotion) and illness comprehensibility.

### **Walking and exercise self-efficacy**

Self-efficacy was measured using the 100% confidence rating scale (from 0% = no confidence to 100% = complete confidence) [55]. This self-efficacy questionnaire will

measure participants' confidence in their ability to walk for 10 minute time periods increasing from 10 minutes to one hour each day. The same scale was also be used to measure participants' confidence in their ability to undertake any other form of exercise. An overall score for walking and exercise self-efficacy is calculated by summing the efficacy scores for each time period divided by the number of time periods. Exercise self-efficacy measures using the 100% confidence rating scale have been shown to have good ( $\alpha > 0.8$ ) internal reliability [56-59].

### **Exercise self-regulatory efficacy**

Participants' confidence in their ability to self-regulate their exercise behaviour in the face of five commonly identified barriers (tired, bad mood, bad weather, lack of time and holiday) was measured [60]. This questionnaire will use the 100% confidence rating scale; an overall score for self-regulatory efficacy is calculated by summing the efficacy scores for each barrier divided by the number of barriers.

## **2.5 Data analysis**

Differences between groups at baseline were analysed using analysis of variance procedures, nonparametric Kruskal-Wallis, and chi-square tests for, respectively, normally distributed continuous data, nonparametric continuous data and categorical data. Associations between variables measured at baseline were analysed using Spearman correlation coefficients.

### 3 Results

In total, 326 individuals were invited to take part in the study of whom 103 individuals (32%) consented to take part. The most common reason given for not wanting to take part in this study was a perceived lack of time or physical disability. Those who took part in the study were of a similar age and ethnicity compared to those who declined the invitation; however, relatively more men than women agreed to take part in the study (63% of the study participants were male compared to 55% of those who were invited to take part;  $p = 0.03$ ).

Table 2 presents the clinical and demographic baseline characteristics of the study participants. The randomization procedure produced equivalent groups. The age of the participants was  $64 \pm 9$  years, just under two thirds were male and almost a third were from a South Asian Ethnic background. Ten percent of the participants were current smokers and over half of the participants were taking medication for high blood pressure or cholesterol levels.

Pedometer data found that participants took an average of  $6346 \pm 3444$  steps per day and 37% were classified as sedentary. Self-reported physical activity data found that the median energy expenditure from moderate-to-vigorous exercise was 2577 MET-min/week (interquartile range = 3759 MET-min/week). Only 15% of participants were classified as sedentary based on their self-reported physical activity levels.

Pedometer counts correlated positively with total self-reported moderate-to-vigorous intensity physical activity ( $\rho = 0.23$ ,  $p = 0.03$ ).



Illness perception scores are presented in Table 3. Study participants reported low levels of perceived affect and symptom load due to IGT. Participants tended to report that their IGT status would be relatively temporary and that they were not emotionally affected by having IGT. Nonetheless, participants were very concerned about having IGT and felt they had moderate levels of control over and knowledge of IGT.

Participants also tended to report that exercise was likely to be an effective method of controlling IGT.

Efficacy scores are presented in Table 3. Self-efficacy beliefs were almost two times higher for walking than for any other type of exercise ( $P < 0.01$ ). Participants also had moderate levels of confidence in their ability to exercise in the face of five common barriers to exercise.

The percentage of participants reporting moderate or extreme problems in each of the five health domains in the EQ-5D were as follows: mobility 28 %; self-care 9 %, usual activities 18%; pain/discomfort 41%; and anxiety/depression 17%. EQ-5D<sub>utility</sub> scores ranged from -0.003 to 1, and the median value was 1.

Table 4 shows the correlations between steps per day, 2-h glucose and measured psychological determinants. Steps per day were significantly correlated with 2-h glucose and walking, exercise and self-regulatory efficacy. There was also a significant correlation between efficacy beliefs and some illness perceptions. In addition, steps per day were significantly correlated with fasting glucose ( $\rho = 0.22$ ,  $p = 0.04$ ), HDL-cholesterol ( $\rho = 0.23$ ,  $p = 0.03$ ), triglycerides ( $\rho = 0.22$ ,  $p = 0.03$ ), body fat percentage ( $\rho = 0.26$ ,  $p = 0.01$ ) and waist circumference ( $\rho = 0.25$ ,  $p = 0.02$ ). There

was also a significant correlation between steps per day and four of the EQ-5D<sub>profile</sub> items; mobility ( $\rho = -0.40$ ,  $p = <0.01$ ), self-care ( $\rho = -0.42$ ,  $p = <0.01$ ), usual activities ( $\rho = 0.38$ ,  $p = <0.01$ ) and pain/discomfort ( $\rho = 0.24$ ,  $p = 0.02$ ). There was no significant correlation between steps per day and illness perceptions.

## **4. Discussion and conclusion**

### ***4.1 Discussion***

This randomized trial is designed to test whether structured education can be used to increase physical activity in individuals identified with a high risk of developing diabetes. Whilst structured education has been widely used for the treatment of diabetes, this approach has not been utilized to target a single health behaviour in at-risk individuals. In terms of promoting physical activity structured education could provide a feasible alternative to traditional counselling techniques that have been tested in primary care with limited success [61]. It may also provide an alternative to other recently developed theory-driven community physical activity programmes, such as the ProActive trial [62] and the Groningen Active Living Model [63] that have utilized more resource-intensive methods of promoting physical activity.

Another important aspect of this study is that it will investigate whether providing participants with a pedometer, personalized steps per day goals and a steps per day log will promote physical activity behaviour change to a greater extent than simply providing participants with general time-based goals and a physical activity diary. This study will therefore address many of the limitations identified by NICE in other pedometer intervention studies [41].

At baseline participants took an average of  $6346 \pm 3444$  steps per day. This is around 40% lower than the average steps per day reported previously in normal weight, overweight and obese individuals in the United Kingdom [64], however this level of ambulatory activity is

similar to that reported in other industrialised countries [65-67], including in individuals diagnosed with type 2 diabetes [68,69].

This study also found that self-efficacy scores were significantly ( $p < 0.001$ ) higher for walking than for any other form of exercise. Given that self-efficacy levels have been shown to be a mediator of physical activity behaviour change [70], promoting walking activity, which is the primary aim of the PREPARE programme, is highly appropriate for this study population.

Along with the key determinants of social cognitive theory, such as self-efficacy, we hypothesized that illness perceptions are important mediators of physical activity behaviour change in individuals identified with IGT. At baseline, this study did not find a link between illness perceptions and physical activity levels. However, as several illness perceptions were associated with walking, exercise and self-regulatory efficacy beliefs, illness perception may form important preconditions to physical behaviour change in individuals with IGT.

This paper has revealed some limitations with the PREPARE programme study making it likely that future results will have limited generalizability. However, despite these limitations, this study will provide important new evidence on whether structured education can be used to promote physical activity in a multiethnic population identified with IGT in a health care setting. Future analysis will examine the effectiveness of the PREPARE programme at increasing physical activity and improving glucose tolerance with follow-up in the short-term (three months and six months) and longer term (twelve months). Analysis will also investigate whether any of the key determinants on which the PREPARE programme was grounded are mediators of behaviour change.

## **4.2 Conclusion**

This study emphasises the need to develop successful free-living physical activity and self-management programmes for individuals with IGT that are appropriate for implementation in a primary health care or community setting and suggests that structured education, aimed targeting perceptions and knowledge of IGT and promoting increased walking activity, may be one such approach.

## **4.3 Practice implications**

The PREPARE programme study will provide evidence for the efficacy of structured education at promoting physical activity and improving health outcomes in individuals identified with IGT. This could have important implications for diabetes prevention initiatives carried out in a primary health care or community setting. Baseline data reported here indicates that walking is the most appropriate form of activity to promote in individuals with IGT. The fact that objectively measured walking activity was associated with glucose control, lipid profile, and markers of adiposity further emphasises the importance of promoting walking activity in this at-risk population. This study also shows that individuals become concerned after being informed they have IGT, therefore it is important to provide this patient group with accessible and accurate information about IGT.

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*Conflict of interest:* There is no conflict of interest to report.

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